



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,203	04/25/2000	SUZANNE DE LA MONTE	0609.4370001	2325

7590 04/27/2006

STERNE KESSLER GOLDSTEIN & FOX
1100 NEW YORK AVENUE NW
SUITE 600
WASHINGTON, DC 200053934

EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
----------	--------------

1635

DATE MAILED: 04/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/380,203	Applicant(s) DE LA MONTE ET AL.	
	Examiner Brian Whiteman	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/4/06, 2/14/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6, 10-13, 35-37, 39-47 and 49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 10-13, 35-37, 39-43, 49 is/are rejected.
- 7) ☒ Claim(s) 44-47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Final Rejection

Claims 1-3, 5, 6, 10-13, 35-37, 39-47, and 49 are pending.

Applicant's traversal and the amendment to claim 1 filed on 1/4/06 is acknowledged and considered by the examiner.

Applicant's argument filed on 2/14/06 that the drawing filed on 1/4/06 is an exhibit and not a replacement drawing is acknowledged and considered by the examiner.

Claim Objections

Claims 44-47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 6, 10-13, and 35-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New Matter rejection:

The limitation 'wherein said DNA molecule which is at least 90% homologous to SEO ID NO: 1 comprises one or more nucleotides corresponding to nucleotides 150, 194-195, 240-241, 243, 244, 255-256, 266-267, 269-271, 276, 279-280, 293-295, 338-340.41 1, 459, 532-533, 591, 633-644, 795-797, 828, 853-854, 876-877, 883, 884-885, 898, 976, 979-980, 999, 1037, 1043-1044, 1092-1096, 1099, or 1116-1119 of SEO ID NO: 1' in instant claim 1 and claims dependent therefrom is not supported by the instant specification. There appears to be no written description of the limitation in the application as filed. See MPEP § 2163.06. Applicant cites page 25, lines 8-24 for support of the limitation. Page 25, lines 8-24 discloses an antisense oligonucleotide comprising one or more nucleotides corresponding to nucleotides 150, 194-195, 240-241, 243, 244, 255-256, 266-267, 269-271, 276, 279-280, 293-295, 338-340.41 1, 459, 532-533, 591, 633-644, 795-797, 828, 853-854, 876-877, 883, 884-885, 898, 976, 979-980, 999, 1037, 1043-1044, 1092-1096, 1099, or 1116-1119 of SEO ID NO: 1. The skilled artisan understands that an antisense oligonucleotide does not encode a protein and an antisense oligonucleotide would have not an activity of AD7c-NTP when over-expressed in neuronal cells. Therefore, there is nothing in the specification that supports the new limitation as set forth in the claims.

"It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 6, 35-37, 39-43, and 49 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/23756 (cited on an IDS). De La Monte teaches a DNA sequence labeled as AD10-7, which on page 5 of the instant specification applicant state that AD7c-NTP cDNA from an AD brain expression library was cloned and referred to AD10-7 and deposited at ATCC under accession no. 69262 and its sequence was published in Figure 16R of WO 94/23756. Applicant further state that the sequence in Figure 16R was published with numerous errors and are labeled SEQ ID NO: 3 and 4 in the instant specification. In view of applicant's assertion on page 5 of the instant specification, the sequence in SEQ ID NO: 1 is the same DNA as the DNA in SEQ ID NO: 3 and 4 but with corrections. See *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) and *Abbott Labs v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1319, 51USPQ2d 1307, 1310 (Fed.Cir.1999). De La Monte teaches linking the cDNA to a heterologous promoter (pages 22-25 and 77). De La Monte teaches the limitation in instant claims 2, 3, 40, and 41 (pages 55-56 and 77). De La Monte teaches the limitation instant claims 5, 6, 42, and 43 (pages 20 and 95-96).

Applicant's arguments filed 1/4/06 have been fully considered but they are not persuasive.

Art Unit: 1635

Applicant argues that the rejection was incorrectly applied to claims 36, 37, 39-43, and 49 because the nucleotide sequence in Figure 16R of the WO document does not encode amino acid sequence of SEQ ID NO: 2 of the present application. The WO document does not disclose a DNA molecule having SEQ ID NO: 1 of the present application.

Applicant's argument is not found persuasive because the product was already known in the prior art as indicated in the instant specification. For example, the applicant asserts that sequence in Figure 16R of the WO document was incorrectly sequenced. See pages 5 and 25 of the specification. The correct sequence for the sequence in Figure 16R is set forth in SEQ ID NO: 1 of the instant application. The discovery of the correct sequence (SEQ ID NO: 1 (DNA) and SEQ ID NO: 2(amino acid sequence)) for the DNA molecule set forth in Figure 16R does not render the old DNA molecule patentably new to the discoverer. See MPEP 2112 (I)-(II). *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

Thus, the rejection remains for the reasons of record.

Response to Arguments

Applicant's arguments, see page 14, filed 1/4/06, with respect to enablement rejection have been fully considered and are persuasive. The rejection of claims 10-13 and 44-47 has been withdrawn because of the amendment to the claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

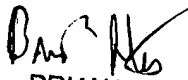
Art Unit: 1635

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635


BRIAN WHITEMAN
PATENT EXAMINER